

Application Serial No. 09/720,762

Attorney Docket No. 114474.00014

Amendment and Response to Final Office Action, Submitted August 5, 2008

Claim 39 (previously presented): The gasket according to claim 33, wherein the pre-filled syringe further comprises a luer lock portion formed in a nozzle of the syringe at an end of the syringe barrel opposite the gasket.

Claim 40 (previously presented): The gasket according to claim 33, wherein a second tapered slant is formed between the peripheral side surface of the gasket that contacts the inner surface of the syringe barrel and the restriction.

Claim 41 (canceled): The gasket according to claim 33, wherein only the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with silicon.

#### REMARKS/ARGUMENTS

Claims 1, 3, 6-9, 11 and 13-40 are now pending, a total of 35 claims. Independent claims 1, 9, 23 and 33 are currently amended. Dependent claims 2, 4, 5, 10, 12 and 41 are canceled.

The Office Action mailed March 5, 2008 rejects claims 1, 3, 6-9, 11 and 13-38 under 35 U.S.C. §112, first paragraph, based on the limitation "wherein the restriction has a height at least one-third the length of the peripheral side surface" recited in independent claims 1, 9, 23 and 33. In addition, claims 1, 3, 6-9, 11, 13-38 are rejected under 35 U.S.C. 103(a).

The March 5, 2008 Office Action fails to address claims 39 and 40, which are currently pending.

#### I. Claim Rejected Under 35 U.S.C. §112

Claims 1, 3, 6-9, 11 and 13-38 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement based on the limitation that "the restriction has a height at least one-third the length of the peripheral side surface." Adequate support for that claim limitation is found in at least Figure 2 of the original

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specification. Without prejudice to or waiving any of its objections to the Examiner's rejections under 35 U.S.C. §112, Applicant has amended independent claims 1, 9, 23 and 33 to recite other features of the invention. Applicant therefore requests withdrawal of the §112 rejections as moot.

## II. Independent Claim 1 (Currently Amended)

Claims 1, 3, 6-9, 16-28 and 30-32 are rejected under 35 U.S.C. §103(a) as being unpatentable over Trull (U.S. 6,080,136) in view of Sudo et al. (U.S. 5,009,646).

Claim 1 is presently amended to recite as follows:

1. A gasket for a pre-filled syringe, the syringe comprising a barrel into which liquid is charged, wherein a peripheral side surface of the gasket that contacts an inner surface of the syringe barrel is provided with a restriction, wherein the restriction has an inner diameter with a ratio of 0.8 or more and less than 1.0 to a diameter of the gasket, and wherein a periphery of a bottom surface of the gasket that is not for contact with the liquid is formed into a tapered slant, and wherein only the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with polyethylene fluoride resin.

Trull does not teach or suggest a laminated gasket. Nor does Trull teach or suggest the desirability of a certain relationship between the diameter of a gasket and the diameter of an annular restriction of the gasket. In the embodiment of Figure 2 of Applicant's disclosure, which is also described at pages 4-5, a ratio of at least 0.8 and less than 1.0 between the diameter (b) of the gasket main body and the diameter (b-2a) of the restriction is shown. With such a ratio, the gasket obtains sufficient rigidity to avoid bending relative to the axis of the syringe barrel and prevent leakage. By contrast, the Trull reference teaches that the so-called "cocking" problem of prior art plungers is overcome by a driving head coupling arrangement

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whereby flexible resilient members at the plunger rear engage a driving head affixed to an injector. (col. 7, line 14 to col. 8, line 9; col. 11, lines 30-35)

Nor does the Sudo reference teach or suggest a specific relationship between the diameters of the gasket and a restriction thereof. Sudo also does not teach to selectively laminate a gasket as recited in amended claim 1, and the Office Action cites no portion of Sudo to the contrary.

For at least the reasons discussed above, the cited references do not teach or suggest a laminated gasket with restriction as recited in amended claim 1.

### III. Independent Claims 9 and 23 (Currently Amended)

Independent claims 9 and 23 are presently amended to recite that "the restriction has an inner diameter with a ratio of 0.8 or more and less than 1.0 to a diameter of the gasket." As discussed above, claims 9 and 23 stand rejected as being unpatentable over the Trull and Sudo references.

However, Trull does not teach or suggest a laminated gasket. Neither Trull nor Sudo identify or describe desired dimensions of the plunger or a restriction thereof. Further, the Trull plunger / driving head arrangement teaches away from use of a restriction of the plunger to prevent bending. For at least the aforementioned reasons, the cited references do not teach or suggest a laminated gasket having a restriction as recited in amended claims 9 and 23.

### IV. Independent Claim 33 (Currently Amended)

Claims 33-38 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Trull and Sudo references in view of Vacca (U.S. 5,531,255).

Independent claim 33 is currently amended, and recites as follows:

33. A gasket for a pre-filled syringe, the syringe comprising a barrel into which liquid is charged, wherein a peripheral side surface of the gasket that contacts an inner surface of the syringe barrel is provided with a restriction,

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wherein the restriction has an inner diameter with a ratio of 0.8 or more and less than 1.0 to a diameter of the gasket, and wherein a periphery of a bottom surface of the gasket that is not for contact with the liquid is formed into a tapered slant, and wherein only the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with silicon.

Independent claim 33, as amended, is patentable over the cited references. Trull does not teach gasket lubrication. Sudo does not teach selective lamination of a gasket. Nor does Vacca. None of the cited reference addresses the relationship between the diameters of the gasket and a restriction portion. For at least the reasons discussed above, the references of record do not teach or suggest applying silicon to a gasket having a restriction as recited in amended claim 33.

#### **V. Dependent Claims**

Dependent claims 3, 6-8, 10-22, 24-32 and 34-40 are patentable with the independent claims set forth above. Those dependent claims recite additional features that further distinguish the invention.

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In view of the foregoing, Applicant respectfully submits that the pending claims are in condition for allowance and requests reconsideration of the application. The Examiner may telephone Applicant's undersigned counsel at the number below concerning this application.

Applicant also encloses a Petition for Extension of Time for two (2) months, and Request for Continued Examination.

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Dated: August 5, 2008

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